PP5F4578

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 26 1996

OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: ***PP5F4578:*** ***Glufosinate-ammonium*** *in/on Transgenic Corn and Soybeans. Amendment Dated June 11, 1996. Submission of Revised Label, Revised Section F, and Additional Residue Data.*
DP Barcode #D227386; **Case** #286934
MRID #s 440333-00, 440333-01, & 440333-02

FROM: María Isabel Rodríguez, Chemist
TPT I/CBTS/HED (7509C)
María I. Rodríguez 8-23-1996

THROUGH: Elizabeth Haeberer, Acting Chief
CBTS/HED (7509C)
Elizabeth T. Haeberer

TO: Donna Davis, Chemical Manager
RCAB/HED (7509C)

The petitioner, AgrEvo USA Company, in letter dated June 11, 1996 from Victor A. Dorr - Manager, Regulatory Affairs - to Joanne I. Miller, is responding to CBTS Review #s 16154/15081 (PP5G4466/5F4578, 3-7-1996, M.I. Rodríguez).

The cited memorandum reviewed data pertaining to a crop destruct Experimental Use Permit [(EUP), #45639-EUP-LA] for the use of Liberty Herbicide on corn and soybeans for the 1996 season, as well as proposed temporary tolerances on those commodities. Additionally, permanent tolerances were also being proposed on the same commodities. At this time the petitioner is addressing issues pertaining only to the permanent tolerance request. A revised label, residue data on aspirated grain fractions, and a revised Section F were submitted for review. Issues pertaining to the EUP/temporary tolerance request (PP5G4466, CBTS #15081)) have already been resolved. CBTS recommended for the EUP and temporary tolerances as of March 26, 1996 (CBTS #17028, #D224369, M.I. Rodríguez).

EXECUTIVE SUMMARY OF RESIDUE CHEMISTRY DEFICIENCIES:

- *None*

RECOMMENDATIONS:

All deficiencies associated with the permanent tolerance

request for use of glufosinate-ammonium in/on transgenic corn and soybeans are considered to be resolved; no additional information is required.

Toxicological considerations permitting, CBTS recommends for the establishment of permanent tolerances for residues of glufosinate-ammonium and its metabolites 2-acetamido-4-methyl-phosphinico-butanoic acid and 3-methylphosphinico-propionic acid expressed as glufosinate free-acid equivalents in/on the following commodities:

Field corn grain, 0.2 ppm
Field corn forage, 4.0 ppm
Field corn stover*, 6.0 ppm
Soybeans, 2.0 ppm
Soybean hulls*, 5.0 ppm
Aspirated grain fractions, 25.0 ppm
Eggs, 0.05 ppm
Poultry, meat, 0.05 ppm
Poultry, fat, 0.05 ppm
Poultry, meat-by-products, 0.10 ppm

* NOTE that although the petitioner proposed a tolerance on "fodder", the proper terminology is now "stover" (see 7-31-1996 Table 1). In the case of soybean hulls, we suggest RD to contact OGC with respect to which section of the FFDCA should be cited to establish this level in light of the recent legislation.

A DRES analysis, as performed for the temporary tolerance petition, will be used for this permanent petition.

DETAILED CONSIDERATIONS:

In response to CBTS's conclusions in CBTS Review #16154 & 15081 (PP5G4466/5F4578, M.I. Rodríguez, 3-7-1996), the petitioner submitted a revised label (Edition #32, dated 6-5-1996), residue data on aspirated grain fractions, and a revised Section F (dated 6-9-1996) for review. The original conclusions, followed by the petitioner's response, and CBTS's comments, will be presented below. Studies with MRID #s 440333-00 and 440333-01 contain administrative material including letter/response from the petitioner, proposed label, and proposed Section F. Study with MRID #440333-02 is an amended report on the magnitude of the residue in/on aspirated grain fractions.

Chemical and company-assigned names/codes and structures of glufosinate-ammonium and its metabolites have been included in the original review of this petition.

* **Conclusion #2(b), CBTS Review #s 16154 & 15081:**

"...The proposed use of glufosinate-ammonium as Liberty Herbicide on Liberty Link corn and soybeans is not adequately described. The label should clearly specify the individual application rate as well as seasonal maxima. Pre-harvest intervals for each plant part (e.g., forage, hay, fodder, grain) in Table II (September 1995) of the Residue Chemistry Guidelines need to be listed. ...the use pattern needs to be supported by the crop residue trials. The feeding/grazing restrictions on treated soybean straw and vines should be deleted from the label as these commodities are not in Table II (September 1995) and tolerances are not required. A plantback interval is also needed for rotational crops [see Conclusion 3(a)(*iii*)]. A revised label should be submitted for review by CBTS."

- **Petitioner's Response to Conclusion #2(b):**

The petitioner submitted a revised proposed label for review.

The proposed label indicates that Liberty Herbicide may be applied at three different rates: 1 pint/acre (0.21 lbs ai/acre), 1.25 pint/acre, and 1.75 pint/acre, depending upon the weed to be controlled and its growth stage; the user is referred to the *Rate Recommendation Tables for Weed Control* section of the label for the appropriate individual application rate. A second application may be needed to control weeds that have not emerged at the time of application. A maximum of two applications per season are permitted for up to 56 ounces of product.

The proposed label states that application(s) should be made when weed growth is between 2 and 12 inches in height; the user is referred to the *Rate Recommendation Tables for Weed Control* section of the label for the appropriate rate and weed size.

The proposed PHIs are as follows: 60 days for corn forage, 70 days for corn grain and fodder, and 70 days for soybean seeds.

The proposed label prohibits the feeding of treated green immature growing soybean plants to livestock.

A plantback interval of 120 days for wheat has been incorporated into the label.

- **CBTS's Comments to Conclusion #2(b):**

The petitioner provided a proposed label for the use of Liberty Herbicide with the requested revisions. The deficiency is considered to be resolved. No additional data or revisions are required from the petitioner on this matter for the permanent tolerance request.

* **Conclusion #3(a)(*iii*), CBTS Review #s 16154 & 15081:**

"...Based on the levels of extractable residues observed at the 119-day plantback interval, no additional data on rotational crops are required provided a 120-day plantback interval is placed on the label. If a shorter plantback interval is desired, field rotational crop studies may be required."

- **Petitioner's Response to Conclusion #3(a)(*iii*):**

A plantback interval of 120 days has been incorporated into the label.

- **CBTS's Comments to Conclusion #3(a)(*iii*):**

The deficiency is considered to be resolved. No additional data or revisions are required from the petitioner on this matter for the permanent tolerance request.

* **Conclusion #8(d), CBTS Review #s 16154 & 15081:**

"...According to Table II (September 1995), corn silage is not considered a food or feed commodity for which tolerances are needed since this commodity is covered by corn forage. Therefore, Section F should be revised to delete that tolerance request. Additionally, Section F should be revised to include CAS names for the chemical names of the parent compound, glufosinate-ammonium, and its metabolites."

- **Petitioner's Response to Conclusion #8(d):**

The petitioner submitted a revised Section F. As requested, the commodity corn silage was deleted from the permanent tolerance request.

The chemical terminology for glufosinate ammonium (and its metabolites) has been revised. As resolved between the Agency and the petitioner in PP8F3607, in which tolerances were established for the tree nut group, almond hulls and animal commodities, the following CAS names are used in the proposed revised Section F. The chemical name for glufosinate-ammonium is monoammonium salt of 2-amino-4-(hydroxymethylphosphinyl)-butanoic acid. The metabolites are 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid. The CAS name for glufosinate-ammonium is also used in the proposed label.

- **CBTS's Comments to Conclusion #8(d):**

The deficiency is considered to be resolved. No additional data or revisions are required from the petitioner on this matter for the permanent tolerance request.

*** Conclusions #10(a)(*ii*)(g) & 10(b)(*ii*)(g), CBTS Review #s 16154 & 15081:**

"The petitioner provided particle size distribution information on the transgenic corn and soybean aspirated grain fractions that showed that less than 5% in most cases had particle size < 400 microns. ...Therefore, the petitioner needs to provide analysis a mixture containing at least 50% of the smaller particles and a revised Section F proposing a permanent tolerance for aspirated grain fractions based on the higher value of the residues found in corn and soybean aspirated grain fractions. ..."

- Petitioner's Response to Conclusions #10(a)(*ii*)(g) & 10(b)(*ii*)(g):

The petitioner generated additional residue data on aspirated grain fractions (AGF). Previously, data on transgenic corn and soybean AGF had been submitted for review. Material preserved from the original transgenic corn study was re-fractionated. The original study, with MRID #437669-26, was reviewed in our previous cited memorandum. The following study was submitted for review:

> Czarnecki, J.J. May 30, 1996. *[Report Amendment] Magnitude of the Residue of Glufosinate-Ammonium in or on Transgenic Field Corn Processed Commodities Following Two Applications of Ignite.* Study Performed by Texas A & M University, College Station, TX and Xenos Laboratories, Inc, Ottawa, Ontario, Canada, and Submitted by AgrEvo USA Company, Wilmington, DE. Lab Project ID #BK-94R-03; Report Amendment No 1, Study Report #A55793. (MRID #440333-02)

Six discrete fractions were obtained. Each fraction was analyzed for residues of glufosinate-ammonium and its metabolites. Approximately 97% of the AGF composite starting material was recovered as individual fractions. The re-fractionation process yielded higher amounts (>80%) of material with a fraction size of <2030 μ; only these particles were utilized in establishing a representative residue value. A total 33-37% of the AGF material was in the <425 μ range compared to less than 5% in the original 1995 study.

Samples kept from the original composite AGF material and the original corn grain samples were re-analyzed to verify storage stability of the glufosinate-ammonium-derived residues for the 11-month storage interval. Overall average residues in the original composite AGF were 3.8 ppm for the 1995 analysis (n=3) and 3.5 ppm for the 1996 analysis (n=5). The maximum residue in the corn grain was 0.34 ppm for the 1995 analysis (n=2) and 0.41 ppm for the 1996 analysis (n=2). Therefore, both the AGF and the corn grain samples are considered to be stable under frozen conditions for up to 11 months.

Method AE-24, a gas chromatographic determination, as described in the Analytical Methodology Section of our previous memorandum, was used to analyze transgenic glufosinate-ammonium-tolerant field corn grain and the AGF. The method was adapted to accommodate a five-fold smaller sample size for the AGF material in order to ensure sufficient amounts for analysis. The LOQ was established at 0.10 ppm. In this study, the method is referred to as BK/05/95. All measured residues are expressed as glufosinate free acid equivalents.

The method was validated for AGF using the original (1995), untreated composite AGF sample. Samples were fortified with 1.0 ppm propionic metabolite and 3.0 ppm parent compound or the disodium-L metabolite. Percent recoveries ranged from 77 to 89% (Average=82%, n=8) for the propionic metabolite, from 87 to 95% (Average=91%, n=2) for the parent compound, and from 98 to 100% (Average=99%, n=2) for the disodium-L metabolite. Results indicate that method performance was adequate using the reduced sample size.

In the present study, fortified samples of the AGF material or corn grain were analyzed within each analytical sample set. Samples were fortified with glufosinate free acid in different combinations: parent plus the propionic metabolite or the disodium-L metabolite plus the propionic metabolite. Fortification levels for the AGF ranged from 0.5 to 1.0 ppm for the propionic metabolite and from 1.0 to 3.0 ppm for the parent compound or the disodium-L metabolite. For the corn grain, fortification recoveries were 0.05 for parent, and 0.05 and 0.10 for each metabolite. Recoveries in the AGF ranged from 75 to 104% (Average=91%, n=16). In corn grain, recoveries ranged from 73 to 105% (Average=92%, n=8). Results indicate that method performance was adequate for analysis of re-fractionated AGF samples and corn grain.

The calculated AGF residue levels are follows.

AGF Particle Size[1] (μ)	**Average Fraction Residue** (*ppm*)	**Percent in AGF Material**[2]	**Composite Residue** (*ppm*)
<425 μ	4.96	50	2.48
425-850 μ	3.67	25	0.92
850-1180 μ	3.10	15	0.47
1180-2030 μ	2.46	10	0.25
Overall AGF Composite Residue (*ppm*) =			4.12

1 Approximate values
2 Proposed composition based on a calculated weighted average.

Residues found in the discrete sample fractions increase with decreasing particle size. The maximum overall AGF composite residue is 4.12 ppm. Therefore, since the maximum residue in the corn grain was 0.41 ppm (1996 study), a concentration factor of 10 is observed. Previously (1995 study), a concentration factor of 12 had been observed.

- CBTS's Comments to Conclusion #10(a)(*ii*)(g) & 10(b)(*ii*)(g):

As observed from the submitted residue data, total glufosinate-ammonium residues concentrated from the field corn grain into the field corn aspirated grain fractions by a factor of 10.

AGF is a composite of various grains. In the case of this permanent tolerance petition, field corn and soybean are the grains to consider. Proposed tolerances for field corn and soybeans are 0.2 and 2.0 ppm, respectively. A concentration factor of 10 is observed for corn. Previously (1995 studies), concentration factors of 12 and 9 were observed for corn and soybeans, respectively. The petitioner has demonstrated that the concentration factor for corn obtained in the 1996 study correlates with that obtained in 1995. The same reasoning could be used for the soybeans concentration factor. Therefore, due to the uncertainty of the AGF composition when the grains are mixed, the appropriate tolerance for the AGF could be calculated using the highest concentration factor (field corn, 12) and the highest proposed tolerance (soybeans, 2 ppm). Therefore, a value of 24 ppm is obtained as appropriate for the AGF tolerance. Consequently, the tolerance proposed by the petitioner, 25 ppm, is considered appropriate.

- Note on Adequacy of Tolerances for Secondary Residues:

Residues in AGF were lower than those obtained in the temporary tolerance petition. Therefore, the existing tolerances for residues in milk and tissues of cattle, goats, hogs, horses, and sheep are adequate. Note in Conclusion #11(c) that poultry tolerances are being re-submitted since they have not been established yet.

As requested (3-7-1996) for the temporary tolerance petition (PP5G4466), a DRES analysis has been performed (5-31-1996, Memo of B. Steinwand to M. Metzger). The tolerance levels for field corn grain, soybeans, and animal commodities for this permanent tolerance request are the same as those used in the DRES analysis for the temporary tolerance petition. Therefore, a new DRES analysis is not required. At the PM's request, a copy of the DRES analysis is attached to this review.

* **Conclusion #10(b)(*i*)(i), CBTS Review #s 16154 & 15081:**

"The petitioner is proposing a tolerance of 1.5 ppm for soybean hulls. The residue data support a Section 701 MRL of 5.0 ppm. Therefore, a Section F proposing such an MRL should be submitted for review for...the...permanent tolerance petition (see Conclusion 8d also)."

- **Petitioner's Response to Conclusion #10(b)(*i*)(i):**

The petitioner submitted a revised Section F. As requested, a Section 701 MRL of 5.0 ppm in/on soybean hulls is being proposed in the permanent tolerance request.

- **CBTS's Comments to Conclusion #10(b)(*i*)(i):**

The deficiency is considered to be resolved. No additional data or revisions are required from the petitioner on this matter for the permanent tolerance request. However, in light of the recent legislation, we suggest RD to contact OGC with respect to which section of the FFDCA should be cited to establish the 5.0 ppm level on soybean hulls.

* **Conclusion #11(c), CBTS Review #s 16154 & 15081:**

"...As of February 1, 1996, tolerances have not been established for residues in eggs and poultry tissues. Revised Sections F should be submitted for...the...permanent tolerance petition proposing tolerances of 0.05 ppm for eggs, poultry meat and poultry fat, and 0.1 ppm for poultry meat-by-products."

- **Petitioner's Response to Conclusion #11(c):**

The petitioner submitted a revised Section F. As requested, tolerances of 0.05 ppm for eggs, poultry meat and poultry fat, and 0.1 ppm for poultry meat-by-products are being proposed in the permanent tolerance request.

- **CBTS's Comments to Conclusion #11(c):**

The deficiency is considered to be resolved. No additional data or revisions are required from the petitioner on this matter for the permanent tolerance request.

Attachment: DRES Analysis (Memo BSteinwand to MMetzger, 5-31-1996, 6 pages)
cc(with Attachment): MIRodríguez, PP5F4578, JMiller/EWilson (7505C), & Reading File.
cc(without Attachment): PP5G4466, JStokes, & Circulation.
RDI: TPT#1 (8-15-96); RALoranger (8-20-1996); EHaeberer (8-22-1996)
MIRodríguez: Draft (8-9-1996), Edited (8-23-1996).
Mail Code 7509C; Tel (703)-305-6710; CM #2, Rm 804-T.

End of Document

Attachment to PPSF4578

Received/filed under PP 5G4466 on 6/4/1996 MDR.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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SCIENTIFIC DATA REVIEWS
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OFFICE OF
PREVENTION, PESTICIDES, AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Glufosinate-ammonium in/on Corn and Soybeans (PP# 5G4466).

FROM: Brian Steinwand BS
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head E.A. Doyle
Dietary Risk Evaluation Section
SAB/Health Effects Division

TO: Mike Metzger, Chief
RCAB (7509C)

Action Requested

Provide a dietary exposure analysis for the use of glufosinate-ammonium in/on field corn (0.2 ppm), soybeans (2.0 ppm), eggs (0.05 ppm), poultry meat (0.05 ppm), poultry fat (0.05 ppm), and poultry meat-by-products (0.1 ppm).

Discussion

For the purposes of this analysis, the new tolerance on almonds was upgraded to pending status.

There presently exists a published tolerance on meat (cattle, goats, horse, sheep and hogs) at the recommended tolerance levels (See PP# 8F3607).

There is also a pending tolerance (See PP# 8F3607) for poultry at the recommended levels.

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.02 mg/kg bwt/day, based on a NOEL of 2.1 mg/kg bwt/day from a two-year rat chronic toxicity study with an uncertainty factor of 100 that demonstrated increased absolute and relative kidney weights in males as an endpoint effect (See memo, G. Ghali, 5/13/92). The RfD has been reviewed by the HED RfD committee (6/24/93).

Currently, a data gap exists for the rat carcinogenicity study (G. Ghali memo, 9/14/93).

Residue Information

Tolerances for glufosinate-ammonium are published in 40 CFR §180.473. Tolerance level residues and 100 percent crop treated assumptions were made for the proposed commodities.

Results

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 2 and 3.

Chronic Exposure Analysis

Exposure from Existing Tolerances for glufosinate-ammonium:

Subgroup	Exposure (mg/kg/day)	%RfD
U.S. Population	0.000416	2.07
Non-Nursing Infants (< 1)	0.002124	10.6

Proposed new Tolerances on the proposed commodities:

U.S. Population	0.000743	3.7
Non-Nursing Infants (< 1)	0.003455	17.2

If the new tolerances on the proposed commodities are approved:

U.S. Population	0.001158	5.7
Non-Nursing Infants (< 1)	0.005579	27.8

Conclusions

The chronic analysis for glufosinate-ammonium is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with glufosinate-ammonium. Thus, the chronic dietary risk exposure to glufosinate-ammonium appears to be minimal for these petitions on corn, and soybeans and does not exceed the RfD for any of the DRES subgroups.

Attachments

cc: DRES; Caswell 580I; J. Miller/E. Wilson, PM Team 23 ; CBTS (M. Rodriguez)

TABLE 1

CHEMICAL INFORMATION FOR CASWELL NUMBER 580I DATE: 05/23/96 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glufosinate-ammonium Caswell #580I CAS No. 77182-82-2 A.I. CODE: 128850 CFR No. 180.31	2yr feeding- rat NOEL= 2.1000 mg/kg 40.00 ppm LEL= 7.6000 mg/kg 140.00 ppm ONCO: Undetermined.	Increased absolute and relative kidney weights in males. Both carcinogenicity studies did not establish an MTD.	ADI UF -->100 OPP RfD= 0.020000 EPA RfD= 0.000400	Oncogenicity- rat Oncogenicity- mouse (Syn.: Ignite, HOE-38966)	EPA verified 02/18/87 WHO reviewed 1991 RfD/PR reviewed 11/08/91 EPA deferred 03/24/92 RfD/PR reviewed 06/24/93 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
01014AA	GRAPES-FRESH (EXP. 7/99)	8F3607			0.050000
01014DA	GRAPES-RAISINS (EXP. 7/99)	8F3607			0.050000
01014JA	GRAPES-JUICE (EXP. 7/99)	8F3607			0.050000
03001AA	ALMONDS	8F3607		0.100000	
03002AA	BRAZIL NUTS (EXP. 7/99)	8F3607			0.100000
03003AA	CASHEWS (EXP. 7/99)	8F3607			0.100000
03004AA	CHESTNUTS (EXP. 7/99)	8F3607			0.100000
03005AA	FILBERTS, HAZELNUTS (EXP. 7/99)	8F3607			0.100000
03006AA	HICKORY NUTS (EXP. 7/99)	8F3607			0.100000
03007AA	MACADAMIA NUTS (BUSH NUTS) (EXP. 7/99)	8F3607			0.100000
03008AA	PECANS (EXP. 7/99)	8F3607			0.100000
03009AA	WALNUTS (EXP. 7/99)	8F3607			0.100000
03010AA	BUTTER NUTS (EXP. 7/99)	8F3607			0.100000
03013AA	BEECHNUTS (EXP. 7/99)	8F3607			0.100000
04001AA	APPLES-FRESH (EXP. 7/99)	8F3607			0.050000
04001DA	APPLES-DRIED (EXP. 7/99)	8F3607			0.050000
04001JA	APPLES-JUICE (EXP. 7/99)	8F3607			0.050000
06002AA	BANANAS-UNSPECIFIED (EXP. 7/99)	2E4057			0.300000
06002AB	BANANAS-FRESH (EXP. 7/99)	2E4057			0.300000
06002DA	BANANAS-DRIED (EXP. 7/99)	2E4057			0.300000
06016AA	PLANTAINS (EXP. 7/99)	2E4057			0.300000
15029AA	SOYBEANS-SPROUTED SEEDS	5G4466	2.000000		
24002EA	CORN,GRAIN-ENDOSPERM	5G4466	0.200000		
24002HA	CORN,GRAIN-BRAN	5G4466	0.200000		
24002SA	CORN SUGAR	5G4466	0.200000		
27010QA	SOYBEANS-OIL	5G4466	2.000000		
28023AA	SOYBEANS-UNSPECIFIED	5G4466	2.000000		
28023AB	SOYBEANS-MATURE,SEEDS DRY	5G4466	2.000000		
28023WA	SOYBEANS-FLOUR, FULL FAT	5G4466	2.000000		
28023WB	SOYBEANS-FLOUR, LOW FAT	5G4466	2.000000		
28023WC	SOYBEANS-FLOUR,DEFATTED	5G4466	2.000000		
43058AA	WINE AND SHERRY (EXP. 7/99)	8F3607			0.050000
50000DB	MILK-NON-FAT SOLIDS	8F3607			0.020000
50000FA	MILK-FAT SOLIDS	8F3607			0.020000
50000SA	MILK SUGAR (LACTOSE)	8F3607			0.020000
53001BA	BEEF-MEAT BYPRODUCTS	8F3607			0.100000
53001FA	BEEF(BONELESS)-FAT (BEEF TALLOW)	8F3607			0.050000
53001MA	BEEF(BONELESS)-LEAN (W/O REMOVEABLE FAT)	8F3607			0.050000
53002BA	GOAT-MEAT BYPRODUCTS	8F3607			0.100000
53002FA	GOAT(BONELESS)-FAT	8F3607			0.050000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glufosinate-ammonium Caswell #5801 CAS No. 77182-82-2 A.I. CODE: 128850 CFR No. 180.31	2yr feeding- rat NOEL= 2.1000 mg/kg 40.00 ppm LEL= 7.6000 mg/kg 140.00 ppm ONCO: Undetermined.	Increased absolute and relative kidney weights in males. Both carcinogenicity studies did not establish an MTD.	ADI UF -->100 OPP RfD= 0.020000 EPA RfD= 0.000400	Oncogenicity- rat Oncogenicity- mouse (Syn.: Ignite, HOE-38966)	EPA verified 02/18/87 WHO reviewed 1991 RfD/PR reviewed 11/08/91 EPA deferred 03/24/92 RfD/PR reviewed 06/24/93 On IRIS.

FOOD CODE	FOOD NAME	PETITION NUMBER	TOLERANCE (PPM) NEW	PENDING	PUBLISHED
53002MA	GOAT(BONELESS)-LEAN (W/O REMOVEABLE FAT)	8F3607			0.050000
53003AA	HORSE	8F3607			0.050000
53005BA	SHEEP-MEAT BYPRODUCTS	8F3607			0.100000
53005FA	SHEEP(BONELESS)-FAT	8F3607			0.050000
53005MA	SHEEP(BONELESS)-LEAN (W/O REMOVEABLE FAT	8F3607			0.050000
55008BA	TURKEY-BYPRODUCTS	8F3607		0.100000	
55008MA	TURKEY-FLESH(W/O SKIN, W/O BONES)	8F3607		0.050000	
55008MB	TURKEY-FLESH(+SKIN,W/O BONES)	8F3607		0.050000	
55013BA	POULTRY,OTHER-BYPRODUCTS	8F3607		0.100000	
55013MA	POULTRY,OTHER-FLESH (+SKIN,W/O BONES)	8F3607		0.050000	
55014AA	EGGS-WHOLE	8F3607		0.050000	
55014AB	EGGS-WHITE ONLY	8F3607		0.050000	
55014AC	EGGS-YOLK ONLY	8F3607		0.050000	
55015BA	CHICKEN-BYPRODUCTS	8F3607		0.100000	
55015MA	CHICKEN-FLESH(W/O SKIN,W/O BONES)	8F3607		0.050000	
55015MB	CHICKEN-FLESH(+SKIN,W/O BONES)	8F3607		0.050000	

TABLE 2

TOLERANCE ASSESSMENT SYSTEM ROUTINE CHRONIC ANALYSIS DATE: 05/23/96 PAGE: 1

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Glufosinate-ammonium Caswell #580I CAS No. 77182-82-2 A.I. CODE: 128850 CFR No. 180.31	2yr feeding- rat NOEL= 2.1000 mg/kg 40.00 ppm LEL= 7.6000 mg/kg 140.00 ppm ONCO: Undetermined.	Increased absolute and relative kidney weights in males. Both carcinogenicity studies did not establish an MTD.	ADI UF -->100 OPP RfD= 0.020000 EPA RfD= 0.000400	Oncogenicity- rat Oncogenicity- mouse (Syn.: Ignite, HOE-38966)	EPA verified 02/18/87 WHO reviewed 1991 RfD/PR reviewed 11/08/91 EPA deferred 03/24/92 RfD/PR reviewed 06/24/93 On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.000415	0.001212	6.058920	3.982100		
U.S. POPULATION - SPRING SEASON	0.000387	0.001158	5.789680	3.855870		
U.S. POPULATION - SUMMER SEASON	0.000408	0.001203	6.015115	3.976040		
U.S. POPULATION - FALL SEASON	0.000437	0.001256	6.281905	4.099150		
U.S. POPULATION - WINTER SEASON	0.000430	0.001230	6.149825	3.997710		
NORTHEAST REGION	0.000438	0.001150	5.747550	3.558405		
NORTH CENTRAL REGION	0.000416	0.001203	6.014410	3.932580		
SOUTHERN REGION	0.000358	0.001179	5.896915	4.109350		
WESTERN REGION	0.000484	0.001365	6.826725	4.406425		
HISPANICS	0.000538	0.001439	7.194340	4.503830		
NON-HISPANIC WHITES	0.000419	0.001208	6.040375	3.946460		
NON-HISPANIC BLACKS	0.000330	0.001125	5.623230	3.974830		
NON-HISPANIC OTHERS	0.000465	0.001246	6.228140	3.901580		
NURSING INFANTS (< 1 YEAR OLD)	0.000895	0.001777	8.883655	4.409150		
NON-NURSING INFANTS (< 1 YEAR OLD)	0.002124	0.005661	28.303265	17.684980		
FEMALES (13+ YEARS, PREGNANT)	0.000280	0.000813	4.064370	2.664170		
FEMALES 13+ YEARS, NURSING	0.000363	0.001043	5.215935	3.403165		
CHILDREN (1-6 YEARS OLD)	0.001166	0.002720	13.598420	7.768515		
CHILDREN (7-12 YEARS OLD)	0.000654	0.001820	9.098165	5.830325		
MALES (13-19 YEARS OLD)	0.000402	0.001232	6.157905	4.148320		
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.000321	0.001012	5.059015	3.452710		
MALES (20 YEARS AND OLDER)	0.000258	0.000883	4.414490	3.122350		
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.000236	0.000792	3.960935	2.779705		

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

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TABLE 3

TOLERANCE ASSESSMENT SUMMARY FOR Glufosinate-ammonium DATE: 05/23/96
CASWELL #580I

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.000416	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	2.077	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.000743	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	3.710	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.001158	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	5.787	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.000055	MG/KG/DAY
THIS TMRC WILL OCCUPY	0.272	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.001212	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	6.059	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING TOLERANCES (PUBLISHED ONLY)		
RESULT IN A TMRC OF:	0.002124	MG/KG/DAY
THE EXISTING TMRC IS EQUIVALENT TO:	10.618	% OF THE ADI.
PROPOSED NEW TOLERANCES (CURRENT PETITION ONLY)		
RESULT IN A TMRC OF:	0.003455	MG/KG/DAY
THESE NEW TOLERANCES WILL OCCUPY:	17.273	% OF THE ADI.
IF THE NEW TOLERANCES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT TMRC WILL BE:	0.005579	MG/KG/DAY
THE NEW TMRC WILL OCCUPY	27.892	% OF THE ADI.
OTHER PENDING TOLERANCES EXCLUDING THE		
CURRENT NEW PETITION HAVE A TMRC OF:	0.000083	MG/KG/DAY
THIS TMRC WILL OCCUPY	0.412	% OF THE ADI.
IF ALL PENDING TOLERANCES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT TMRC WILL BE:	0.005661	MG/KG/DAY
THE TOTAL TMRC WILL OCCUPY	28.303	% OF THE ADI.

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